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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,897	04/02/1999	KATSUMI AOYAGI	4047	1769

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/269,897	AOYAGI ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,11,12,34,37,38 and 41-47* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,11,34,37,38 and 41-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7/31/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-15-2006 has been entered.

The amendment filed on 11-15-2006 is acknowledged. Claims 11, 37 and 41 have been amended. Claims 42-47 have been added. The amendment filed on 11-20-2006 is acknowledged. Claims has been acknowledged. Claims 4, 11-12, 34, 37-38 and 41-47 are pending. Claim 12 remains withdrawn from consideration. Claims 4, 11, 34, 37-38 and 41-47 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 7-31-2006 has been considered. An initialed copy is attached hereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 11, 34, 37-38 and 41-47 are rejected under 35 U.S.C. 1 12, first paragraph, because the specification, while being enabling for methods of detecting HCV in a biological sample by treating said sample with a "treatment solution" and a "reaction buffer" wherein said "treatment solution" inactivates antibodies present in the sample and consists of guanidine hydrochloride, HCL, Triton X 100 and Tween 20 and wherein the reaction buffer consists of 100 mM sodium phosphate buffer, pH 7.3, containing 0.15 M NaC1, 1% BSA, 0.5% Casein-Na, 0.05% Tween 20 and 1 M Tris (as defined on page 48 of the specification), does not reasonably provide enablement for methods of detecting HCV utilizing treatment solutions or reaction buffers other than those set forth above or any methods for detecting for essentially the reasons set forth in the previous Office action in the rejection of claims 4, 11, 34, 37-38 and 41.The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims is maintained for reasons of record.

Applicant argues:

1. The SDS concentration disclosed in the Declaration filed 2-8-2006 (1.25%) reflects the diluted concentration.

2. The specification discloses that "a treatment agent containing a surfactant other than a anionic surfactant such as SDS can weaken the denaturing effect of SDS on the immobilized antibody and, as a result, enhance sensitivity...".

3. Example 4 exhibits the effects of CHAPS, (amphoteric surfactant), urea (protein denaturant) and Triton-X (nonionic surfactant).

4. The Declaration of 2-8-2006 points out that a conventional buffer can be used in the instant method.

5. The buffer disclosed in the Declaration of 2-8-2006 is a minor modification of the buffer disclosed in the cited reference by Aoyagi et al.

6. Where 5% SDS is mixed with the same amount of serum there is a high probability that most of the SDS would bind to proteins in the serum leaving little SDS to denature the antibody probe.

7. The specification on page 9 discloses the "treatment" of both HCV and HBV viruses.

8. Example 14 discloses the use of a reaction buffer, which is a conventional buffer, in a method to measure HBV core antigen.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, if the values disclosed in Table A of the Declaration filed 2-8-2006 reflect the final concentrations, then the concentrations of all the other components do not reflect the concentrations disclosed in the specification.

With regard to Point 2, the cited portion of the declaration describes a possible means of action for SDS but is silent with regard to the specific concentrations needed to meet all the limitations of the claims (i.e. the conditions that inactivate endogenous antibodies but not the antibody probe).

With regard to Point 3, the cited portions of the specification address the effects the concentration of CHAPS, urea and Triton X 100 on the ability to detect a "probe antibody" but is silent as to the effects said concentrations have on serum antibodies.

With regard to Point 4, the Declaration states that volume of the reaction buffer is conventional not that the buffer itself is conventional.(see points 4-6 of the declaration).

With regard to Point 5, disclosed the Aoyagi et al. reference was not disclosed to inactivate endogenous antibodies but not the antigen or antibody probe. It is was merely shown to have efficacy as an ELISA buffer.

In response to Point 6, , it is noted that the features upon which applicant relies (i.e., that the amount of SDS and serum are equal [v/v]) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, if at a concentration of 5%, SDS binds all the protein in serum, it would necessarily bind (and denature) the viral antigen to be detected.

With regard to Points 7 and 8, the specification discloses no examples detecting HBV utilizing the **combination** of a "treatment solution" and a "reaction buffer". The only Example drawn to HBV utilizes a "treatment solution" only. Moreover the specification is silent as to what constitutes the "reaction buffer" in Example 14 or whether said preferentially denatures serum antibodies but not the viral antigens or probe antibodies.

As outlined previously, the instant claims are drawn to methods of detecting HCV or HBV in a biological sample by treating said sample with a "treatment solution" wherein said "treatment solution" inactivates antibodies present in the sample (see step 1 of claimed methods). Said sample is then subjected to an immunoassay that utilizes an antibody probe after the treated sample is added to a reaction buffer. The specification gives no guidance as to what combination of components, other than those set forth above, would result in a treatment solution that would inactivate the endogenous

antibodies present in the biological sample (step 1 of the claimed methods) but not inactivate the antibody probe subsequently used in the immunoassay (step 2 of the claimed methods). Moreover, the specification is silent as to what, other than those components set forth on page 48 of the specification, constitute a "reaction buffer". The specification is equally silent on which antibody probes, if any, would be impervious to the inactivating properties of the claimed "treatment solution". Applicant has argued, "Applicant has been able to detect an antigen of HCV and HBV with a high degree of sensitivity". However, contrary to that assertion, only one working example (example l 0) utilizes both a reaction solution and a reaction buffer. While the skill in the art of immunology, chemistry and protein chemistry is high, one of skill in the art would not be able to contemplate what combination of treatment solution components, reagent buffer components and antibody probe (other than those set forth above) would meet the limitations of the claimed methods since the antibody probe (which must remain functional in order to be used to detect viral antigens in the immunoassay) and the endogenous antibodies (which must be inactivated) are exposed to the identical conditions. Since, one of skill in the art would not readily be able to predict the effects of a given solution (i.e. that the solution inactivated the endogenous antibodies present in the sample but not inactivate any antibody probe), he/she would not be able to make the treatment solution or reaction buffer (other than those set forth above) needed to perform the claimed method without undue experimentation. Consequently, the specification is only enabling for methods of detecting HCV in a biological sample by treating said sample with a "treatment solution" and a "reaction buffer" wherein said "'treatment solution" inactivates antibodies present in the sample and consists of guanidine

hydrochloride, HCL, Triton X 100 and Tween 20 and wherein the reaction buffer consists of 100 mM sodium phosphate buffer, pH 7.3, containing 0.15 M NaCl, 1% BSA, 0.5% Casein-Na, 0.05% Tween 20 and 1 M Tris (as defined on page 48 of the specification). It should be noted that the concentrations of solution components in HBV and HCV solutions differ (see Examples 4, 5, 6, 10 and 14). Moreover, the specification discloses no examples detecting HBV utilizing the combination of a "treatment solution" and a "reaction buffer". The only Example drawn to HBV utilizes a "treatment solution" only. Consequently, the specification is not enabling for any method of detecting HBV.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Mon - Thur. 7am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PRIMARY EXAMINER

February 19, 2007